

Interview Summary

Applicants' representative thanks Examiner Johnson for the courtesy of granting a telephonic interview conducted August 9, 2005.

Applicants' representative addressed the rejections under § 112 by providing background information regarding the IRM compounds described in Applicants' disclosure, including immunological mechanisms of action and the importance of TLR agonist activity.

Applicants' representative addressed the rejection under § 103 by reiterating and clarifying the position set forth in Applicants' previous Amendment and Response.

Finally, Examiner Johnson expressed concern that the application provided data from only a single subject.

No agreement was reached, although Examiner Johnson indicated that he would reconsider the rejections under §§ 103 and 112 in light of comments made during the interview, which form the basis of the remarks provided below.

Remarks

Claims 1-22 are pending in the application. Claims 16-22 have been canceled. Consequently, Claims 1-15 are under consideration.

Claim 1 is amended herein.

Applicants respectfully request reconsideration of the application in view of the amendments, the accompanying Affidavit of Peter T. Elliott, the data attached thereto, and the following remarks, which are limited to the claims remaining under consideration.

Amendments to the Claims

Please cancel claims 16-22 without prejudice.

Claim 1 has been amended to recite a method for removing a mature tattoo comprising: treating at least a portion of a tattooed region comprising a mature tattoo with a cell disrupter; and administering to at least a portion of the tattooed region an amount of an IRM compound effective for fading the tattoo.

The amendments are fully supported by the specification. The amendment reciting a treatment of a mature tattoo is supported at, for example, page 11, lines 6-17. The amendment reciting “an amount of an IRM compound effective for fading the tattoo” is supported at, for example, page 13, lines 17-19.

No new matter is introduced by these amendments.

§ 112 Rejections

Claims 1-15 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the claims contain subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Specifically, the Office Action notes that while many different IRM compounds are disclosed and claimed, the only testing was done with imiquimod.

Applicants respectfully traverse the rejection. Imiquimod and IRM compounds in the other described classes are known to act through common immunological mechanisms involving Toll-like receptors (TLRs). While the combination of laser therapy and immunotherapy to remove mature tattoos is novel, the full scope of the claimed method is founded on established

immunological technology based on a mechanism of action shared by all TLR agonists in the recited compound classes. Consequently, those skilled in the art having the knowledge that imiquimod is effective in combination with laser therapy or removing mature tattoos would know that IRM compounds in the recited classes would also be effective. Therefore, the example not only enables the claimed methods using imiquimod, but does so for the full scope of the claimed methods using TLR agonist IRM compounds from the recited compound classes.

The Office Action also asserts that the claimed methodology is a nascent technology requiring more specific teachings for enablement. Applicants submit that the claimed methods rely on established knowledge of IRM compounds as immunomodulatory compounds and TLR agonists—e.g., mechanisms of action, relative potencies, cytokines induced, etc. Accordingly, one skilled in the art of immunology—even dermatology, a field in which use of imiquimod is well-established—would be able to determine an effective amount of IRM compound to fade a mature tattoo based on Applicants' example and teaching at, for example, page 13, lines 23-30 and page 14, lines 1-7.

Thus, the example of Applicants disclosure provides, combined with the knowledge of those skilled in the art regarding imiquimod, related IRM compounds, and their common mechanisms of action, provide adequate predictability of results for the full scope of the claimed compounds without undue experimentation.

Withdrawal of the rejection of claims 1-15 under 35 USC § 112, first paragraph is respectfully requested.

Claim 1-15 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action states that “an effective amount” lacks definite bounds and is indefinite. Applicants submit that the phrase “an effective amount” is not indefinite *per se*. More than 79,000 United States patents in the chemical, biomedical, pharmaceutical, etc. arts have issued with the term “an effective amount” in the claims. Another 10,000 patents have issued with the related language “in an amount effective to” recited in the claims.

Furthermore, Applicants have defined what is considered effective (page 13, lines 17-22), provided exemplary ranges of effective doses (page 14, lines 1-7), and factors those skilled in the art would consider to determine an effective amount in any given application (page 13, lines 23-

33). This information, combined with the knowledge of those skilled in the art regarding imiquimod, related IRM compounds, and their common mechanisms of action, render use of term “an effective amount” in the claims definite.

Withdrawal of the rejection of claims 1-15 under 35 USC § 112, second paragraph is respectfully requested.

§ 103 Rejections

Claims 1-8 and 11-15 stand rejected under 35 USC § 103(a) as being unpatentable over Anderson in view of Solis *et al.* Anderson teaches laser disruption of mature tattoos, which releases laser-altered ink into the dermis (p. 210, second column). Solis *et al.* teaches use of topical imiquimod to remove acute phase tattoos—treatment beginning six hours after the tattoo was placed. The Office Action asserts that it would have been obvious to combine the teachings of Anderson and Solis *et al.* to arrive at the claimed invention. The Office Action further comments that (a) Solis *et al.* states that it is unknown if a laser would re-create biological elements of the acute phase tattoo, and (b) Anderson essentially answers that question, thereby motivating the combination of the references.

Applicants respectfully disagree with the position stated in the Office Action. Anderson states that the released ink is laser-altered. Thus, Anderson cannot be said to re-create the biological elements of an acute phase tattoo—the ink is altered from its condition when the tattoo is first applied. Neither Anderson nor Solis *et al.* provide any teaching regarding whether use of an IRM compound promotes clearance of *laser-altered* tattoo ink.

Moreover, Solis *et al.* was published almost one year *after* Anderson. Thus, if Anderson essentially answered the question raised in Solis *et al.*, as asserted in the Office Action, then why would the question in Solis *et al.* be raised? Almost a year after Anderson was published, Solis *et al.* still stated that it is still unknown if their treatment regimen would have any efficacy on more established tattoos. By itself, Solis *et al.* undermines any reasonable expectation of success that is required of one skilled in the art in order for a rejection under 35 USC § 103 to be proper.

Also, Anderson recounts a pilot study that attempted to increase efficacy of tattoo image removal by the same cellular mechanism induced by IRM compounds—i.e., increased phagocytosis by mobile inflammatory cells (Anderson p. 210, column 2- p. 211, column 1)—and

the same mechanism speculated to be at work in Solis *et al.* (p.83, column 1 to column 2).

Anderson states, “Again, unfortunately, this did not improve efficacy.” (p.211, column 1, lines 2-3). By itself, Anderson also undermines any reasonable expectation of success that is required of one skilled in the art in order for a rejection under 35 USC § 103 to be proper.

Thus, *both* references undermine any expectation of success if one skilled in the art were motivated to combine the references as suggested in the Office Action. Taken together and read as a whole, the cited references provide no reasonable expectation of success combining and IRM compound with laser therapy to remove mature tattoos.

The rejection of claims 1-8 and 11-15 under 35 USC § 103(a) as being unpatentable over Anderson in view of Solis *et al.* is improper and should be withdrawn.

Affidavit of Peter T. Elliott

Finally, in response to the concern stated during the interview that the application provides data from only a single patient, Applicants’ provide attached hereto an affidavit of Peter T. Elliott for the purpose of submitting twelve pages of preliminary clinical data regarding the use of an IRM compound in combination with laser therapy in order to fade tattoo images.

The preliminary data include photographs of twenty-four tattoos from patients currently participating in a clinical study being conducted at Wake Forest University. The clinical study is ongoing and thus some patients have not completed their course of therapy (marked as “pending” in the attached photographs). The clinical study is expected to be completed by the end of June 2006, at which time a full statistical analysis of double-blinded independent evaluations of all photographs by trained dermatologists will be available in support of the application.

It is apparent from the preliminary photographs that some tattoos are at least substantially, and in some cases almost entirely, faded under the “Aldara” treatment regimen after only one or two laser sessions. This result is apparent for primarily black/blue tattoo images (e.g., F.S. 1101019; M.S. 1814845; M.S. 1562946; and S.B. 1832810) and for tattoo images containing multiple colors (e.g., L.S. 1801751 and L.M. 386780). Consequently, Applicants submit that the claimed treatment is effective generally and not merely for the single patient exemplified in Applicants’ disclosure.

Conclusion

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application and allowance of claims 1-15 is requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that doing so may assist prosecution of this application.

Respectfully submitted,

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Date

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